

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

---

In re Patent Application of:  
James D. Marks

Application No.: 09/556,945

Art Unit: 3626

Filed: April 21, 2000

Examiner: Robert W. Morgan

For: **SYSTEM AND METHOD FOR  
RECRUITMENT OF CANDIDATES FOR  
CLINICAL TRIALS WHILE MAINTAINING  
SECURITY**

---

**DECLARATION OF JAMES D. MARKS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, James D. Marks, hereby declare and state as follows:

1. I am a citizen of the United States and am more than twenty-one years of age.

2. I am the Founder and Chief Executive Officer of Body Health Resources Corporation ("BHRC").

3. I am the inventor of the patent application identified above and I am the inventor of the subject matter described and claimed therein. I have read the publication, "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet," PR Newswire, June 28, 1999 (the "drkoop.com press release"). Prior to June 28, 1999, I had completed my invention as described and claimed in the subject patent application in the United States. The following paragraphs describe the relevant work that was completed by me, along with individuals working on my behalf

and under my supervision and control. The work completed prior to June 28, 1999 explicitly teaches each element of each independent claim rejected in the Office Action dated May 19, 1999 based on the drkoop.com press release, to which the Amendment accompanying this Declaration responds.

4. I conceived of, supervised and controlled the design and implementation of web site pages on www.thebody.com on which BHRC was presenting a Health Survey Questionnaire and accompanying information about the purpose and use of the Questionnaire (including information about the protection of privacy of the respondents and confidentiality of the responsive data). The purpose of the Health Survey Questionnaire was to solicit health and contact information from members of the public, provided with gratuitous access to the web site, for possible participation in one or more upcoming clinical trials. The Health Survey Questionnaire was first installed on a server for posting on www.thebody.com and made accessible to members of the public through access to www.thebody.com via the Internet between May 21, 1999 and, at the latest, May 24, 1999, the first date for which www.thebody.com received responses to the Questionnaire (see Exhibit C). The launch date and receipt of responses from the Health Survey Questionnaire is prior to the June 28, 1999 publication of the drkoop.com press release.

5. I further conceived of, supervised and controlled the design and implementation of a secure database in which the data entered in response to the Health Survey Questionnaire was stored. The first responses to the Questionnaire were received on May 24, 1999. The data received on May 24, 1999 was accessed, printed and stored by Dahlia Elsayed, an employee of Body Health Resources Inc at the relevant time, based on instructions from Bonnie Goldman, who was at the time a consultant.

6. Attached as Exhibits A, B and C are evidence of the Health Survey Responses received by www.thebody.com prior to June 28, 1999. More particularly,

a. Attached as Exhibit A is a true copy of the jacket cover

from the zip disk containing the Health Survey Responses for responses for the initial responses which were received from May 24, 1999 to April 12, 2000. The jacket cover contains the hand written description of the contents as "Health Survey Responses... launched 5/25/99."

b. Attached as Exhibit B is a true copy of the file index listing of the zip disk of Exhibit A. The index includes: column 1 provides the file name which corresponds to the date the Health Survey Responses data was saved to the disk; column 2 provides the time stamp for saving the file; column 3 provides the storage amount of the data; and, column 4 provides the extended name of the file.

c. Attached as Exhibit C is a true copy of a hard copy listing of the Health Survey Responses from May 24, 1999 to June 27, 1999, with redaction of specific data.

i. Each response contains a "Date Submitted" field which provides the date of data entry. The hard copy listing includes only a portion of the files listed on the zip disk file index (Exhibit B) because only those responses prior to June 28, 1999 are relevant.

ii. The earliest responses were submitted on May 24, 1999. There are two May 24, 2004 responses, one is a test response submitted by one of BHRC's employees via the public interface at [www.thebody.com](http://www.thebody.com) and the other is from a member of the public unaffiliated with BHRC. In addition, at least two of the responses from May 25, 2004 are from members of the public unaffiliated with BHRC. Therefore, responses to the Questionnaire by multiple members of the public were received prior to the June 28, 1999 publication date of [drkoop.com](http://drkoop.com) press release.

iii. Each response contains a series of predetermined questions with answers provided by the respondent. Answers which could reveal confidential information of respondents has been redacted for this exhibit in order to maintain the privacy of the respondents and the confidentiality of the data. The redacted data from responses submitted prior to June 28, 1999 was personal contact and medical information from members of the public and such data was received from {W:\03042\000g956us0\00239747.DOC [REDACTED]}

at least two members of the public. Therefore, the secure database generated from responses to the Questionnaire dated May 24, 1999 and May 25, 1999 contained personal contact and medical information from at least two members of the public who provided electronic consent to volunteer for consideration as a potential candidate for existing and future clinical trials.

iii. In order to submit the data which appears in the responses of Exhibit C to [www.thebody.com](http://www.thebody.com), each respondent had to provide electronic consent to a Participation Agreement. The Participation Agreement required that the respondent consent to volunteer for consideration as a potential candidate for existing and future clinical trials. Failure to provide electronic consent to the Participation Agreement precluded submission of the response so that no response would be generated. As a result, each response in Exhibit C corresponds to a respondent who provided electronic consent to volunteer for consideration as a potential candidate for existing and future clinical trials.

iv. The hard copy responses of Exhibit C were generated by Dahlia Elsayed; she attests to their authenticity in her declaration. The redactions of selected data contained in the responses were performed by Jason Dewey, an employee of BHRC; he attests to the purpose of the redactions and the contents of the redacted data in his declaration.

7. In addition, I oversaw the design and publication of a public announcement of the Health Survey Questionnaire which were available to the members of the public unaffiliated with BHRC prior to the June 28, 1999 [drkoop.com](http://drkoop.com) press release. Attached as Exhibit D is a true copy of a notice dated May 26, 1999 announcing the Health Survey Questionnaire to members of the public who were subscribers to the e-newsletter of [www.thebody.com](http://www.thebody.com). I declare that this text was transmitted via e-mail to members of the public who subscribed to the e-newsletter of [www.thebody.com](http://www.thebody.com). I further declare that I am aware of at least one member of the public unaffiliated with BHRC, who received the e-newsletter on May 26, 1999.

8. I further declare that all statements made herein are of my own

knowledge and are true, and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the instant application or of any patent issued thereupon.

Dated: August 19, 2004

  
\_\_\_\_\_  
James D. Marks